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Attachment 5
510(K) Summary
Cutera QSwitch Laser System

JUN 22 2011

This 510(K) Summary of safety and effectiveness for the Cutera QSwitch Laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Cutera, Inc.
Address:	3240 Bayshore Blvd. Brisbane, CA 94005
Contact Person:	Connie Hoy
Telephone: Fax: Email:	415-657-5592 – phone 415-715-3592 – fax choy@cutera.com
Preparation Date:	October 4, 2010
Device Trade Name:	Cutera QSwitch Laser System
Common Name:	Nd:YAG Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	RevLite Q-Switched Nd:YAG Laser System K083899
Description of the Cutera QSwitch Laser System:	The Cutera QSwitch Laser unit and controls are contained in a singleconsole. Electrical power is supplied to the console by the facility's power source. Laser energy produced within the device is delivered to the tissue by means of an articulated arm and a specially designed Multiple Spot Handpiece (532 nm and 1064 nm). The user activates laser emission by means of a footswitch. The Cutera QSwitch Laser is designed to provide laser energy for use in a variety of dermatological procedures. The 532 nm and 1064 nm wavelengths are absorbed by pigment and other chromophores within the skin to create the desired clinical effect. The laser incorporates very narrow laser pulses (5-20 ns) designed to apply higher peak power over a very short period to minimize the time to absorb heat into the tissue.

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Cutera QSwitch Laser System

Intended use of the Cutera QSwitch Laser System:	General: Incision, Excision, Ablation and Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis. Specific: For use for the following indications: Treatment of Epidermal Pigmented Lesions, Treatment of Dermal Pigmented Lesions, Nevus of Ota, Laser skin resurfacing procedures for the treatment of acne scars and wrinkles, Tattoo Removal, Treatment of Vascular Lesions, Removal or lightening of unwanted hair and treatment of Benign Cutaneous Lesions.
Performance Data:	None
Results of Clinical Study:	None

Summary of Technological Characteristics:

	Cutera, Inc. Q-Switched Laser	**RevLite Q-Switched Nd:YAG Laser**
Wavelength	532nm	532nm
Max delivered Energy @end of articulate arm with no handpiece	500mJ	500mJ
Spot Size	2mm -6mm	2mm -6mm
Maximum Fluence @ 2mm spot	5J/cm2	5J/cm2
Maximum Fluence @ 6mm spot	1.5J/cm2	unknown
Pulse Width	5-20ns	5-20ns
Rep Rate	Single shot, 1,2,5 and 10 pulses per second (Hertz)	Single shot, 1,2,5 and 10 pulses per second (Hertz)
	Cutera, Inc. Q-Switched Laser	**RevLite Q-Switched Nd:YAG Laser**
Wavelength	1064nm	1064nm
Max delivered Energy @end of articulate arm with no handpiece	1.6J	1.6J
Spot Size	3mm -8mm	3mm -8mm
Maximum Fluence @ 3mm spot	12J/cm2	12J/cm2
Maximum Fluence @ 8mm spot	3.5J/cm2	unknown
Pulse Width	5-20ns	5-20ns
Rep Rate	Single shot, 1,2,5 and 10 pulses per second (Hertz)	Single shot, 1,2,5 and 10 pulses per second (Hertz)

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Conclusion:

The Cutera QSwitch Laser System is substantially equivalent to the RevLite QSwitch Nd:YAG Laser. (K083899). The Cutera QSwitch Laser is system substantially equivalent in terms of indication for use and technology based on technical characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 2 2 2011

Cutera, Inc.
% Ms. Connie Hoy
3240 Bayshore Boulevard
Brisbane, California 94005

Re: K102954
Trade/Device Name: Cutera QSwitch Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 26, 2011
Received: May 31, 2011

Dear Ms. Hoy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number (if known): (K)102954

Device Name : Cutera QSwitch Laser System

Intended Use: Incision, Excision, Ablation, Vaporization of Soft Tissue for General Dermatology, Dermatologic and General Surgical Procedures for Coagulation and Hemostasis.

Indications for Use:

1064 nm wavelength

- Tattoo Removal (dark ink: blue and black)
- Nevus of Ota
- Removal or lightening of hair with or without adjuvant preparation.
- Skin Resurfacing for Acne Scars and Wrinkles
- Benign cutaneous lesions, such as, but not limited to: striae and scars
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar

532 nm wavelength

- Tattoo removal (light ink: red, sky blue, green)
- Vascular lesions including but not limited to: port wine birthmarks, telangiectasias,
- spider angioma, cherry angioma, spider nevi
- Epidermal Pigmented lesions including but not limited to: cafe-au-lait birthmarks, solar lentiginos, senile lentiginos, Becker's nevi, Freckles, Nevus spilus
- Skin Resurfacing for Acne Scars and Wrinkles
- Benign cutaneous lesions, such as, but not limited to: striae and scars
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar

Prescription Use ___xx___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for mam

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102954